

Attorney Docket No.:       **DEX-0172**  
Inventors:                   **Salceda et al.**  
Serial No.:                   **09/763,978**  
Filing Date:                  **April 25, 2001**  
Page 8

**REMARKS**

Claims 14, 21, 22, 23, 24, 25, 26, 27, 28, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48 and 49 are pending in the instant application. Claims 14, 21, 22, 23, 24, 25, 26, 27, 28, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48 and 49 have been rejected. Claims 24, 28, 38, 39, 40, 44, 45 and 46 have been amended. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Rejection of Claims under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph**

Claims 14, 21-28 and 35-49 remain rejected under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph as the Examiner suggests that the claimed invention is not supported by either a substantial utility or a well established utility.

Claims 14, 21-28 and 35-49 also remain rejected under 35 U.S.C. 112, first paragraph for failing to meet the written description requirement.

Applicants respectfully traverse these rejections.

Attorney Docket No.:       **DEX-0172**  
Inventors:                   **Salceda et al.**  
Serial No.:                  **09/763,978**  
Filing Date:                **April 25, 2001**  
Page 9

The Examiner disagrees with Applicants' argument that the protein encoded by SEQ ID NO:1 is implicit in teachings of the specification. Specifically, the Examiner disagrees because the Declaration submitted by Applicants showed multiple reading frames are identified using the tools available and one of skill in the art would have no reason to assume that the largest open reading frame identified by a computer program would be the protein encoded by SEQ ID NO:1.

However, the case law and MPEP are clear; the examiner must weigh **all** (emphasis added) the evidence before him or her, including the specification and any new evidence supplied by applicant with the evidence and/or sound scientific reasoning previously presented in the rejection to decide whether the claimed invention is enabled (MPEP 2164.05) and useful (2107.02). It is respectfully submitted that the Examiner's suggestion that the protein encoded by SEQ ID NO:1 is not implicit in teachings of the specification because multiple reading frames are identified using the tools available and one of skill in the art would have no reason to assume that the largest open reading frame identified by a computer program would

Attorney Docket No.:       **DEX-0172**  
Inventors:                   **Salceda et al.**  
Serial No.:                  **09/763,978**  
Filing Date:                **April 25, 2001**  
Page 10

be the protein encoded by SEQ ID NO:1 is indicative of the Examiner's failure to weigh all the evidence before him.

Not only is the native protein encoded by the longest open reading frame (ORF) of SEQ ID NO:1, but the ORF begins with the functional protein transcription initiator codon commonly referred to as the Kozak consensus sequence (see Kozak, M. Nucleic Acids Research 1981 9(20):5233-5262; Kozak, M. Nucleic Acids Research 1984 12(2):857-872; and Kozak, M. Nucleic Acids Research 1987 15(20):8125-8148). Further, the ORF begins at the 5'-proximal ATG in SEQ ID NO:1, the initiator codon for the majority of mRNAs.

Both the Kozak consensus sequence and 5'-proximal ATG are well-known characteristics of the coding sequence of nucleic acids and therefore need not be expressly outlined in the specification. See MPEP 2164.05(a) which states that the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is already available to the public.

Further, Applicants have submitted a Declaration of one of skill in the art stating that "we know that the open reading frame in the forward direction of SEQ ID NO:1 would be a frame encoding a Methionine near the 5' end, encode

Attorney Docket No.:       **DEX-0172**  
Inventors:               **Salceda et al.**  
Serial No.:               **09/763,978**  
Filing Date:              **April 25, 2001**  
Page 11

many amino acids and terminate with a stop codon" (see paragraph 6 of Dr. Salceda's Declaration). Submitted with this Declaration is data generated from ORF Finder program (Figure 3 of Dr. Salceda's Declaration) which lists the longest open reading frame **first** when displaying the results. Thus, contrary to the Examiner's suggestion, one of skill in the art does have reason to believe, absent evidence otherwise, that the largest open reading frame identified by a computer program for a selected nucleic acid sequence is the ORF encoding the protein.

Thus, the structures and features of SEQ ID NO:1, coupled with the tools available at the time of filing the instant application to identify the open reading frame in a nucleic acid sequence, clearly provides sufficient information to enable one of skill in the art to make and use the instant claimed invention, thus meeting the requirements of 35 U.S.C. 112, first paragraph, with respect to the enablement and the utility requirements of 35 U.S.C. 101.

Further, teachings of SEQ ID NO:1 with a single Kozak consensus sequence flanking the longest open reading frame in the nucleic acid sequence which begins at the 5'-

Attorney Docket No.:       **DEX-0172**  
Inventors:                   **Salceda et al.**  
Serial No.:                  **09/763,978**  
Filing Date:                **April 25, 2001**  
Page 12

proximal ATG of the disclosed nucleic acid sequence clearly conveys with reasonable clarity to those skilled in the art, as of the filing date, that inventors were in possession of the instant claimed invention. Accordingly, the specification also meets the written description requirements of 35 U.S.C. 112, first paragraph. See MPEP 2163.02.

Reconsideration and withdrawal of these rejections in light of **all** teachings in the specification and **all** evidence submitted during prosecution of this case, is therefore respectfully requested.

**II. Rejection of Claims 24-28, 35-41 and 44-49 under 35 U.S.C. 112, second paragraph**

Claims 24-28, 35-41 and 44-49 have been rejected under 35 U.S.C. 112, second paragraph. The Examiner suggests that there is insufficient antecedent basis for the limitation of "the native protein".

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims to simply state "native protein" to eliminate any confusion. This amendment is believed to overcome any issues relating to antecedent basis.

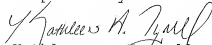
Attorney Docket No.: DEX-0172  
Inventors: Salceda et al.  
Serial No.: 09/763,978  
Filing Date: April 25, 2001  
Page 13

Withdrawal of this rejection is therefore respectfully requested.

### III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Reg. No. 38,350

Date: August 18, 2007

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515